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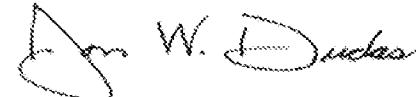
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APPLICATION NUMBER: 60/521,148

FILING DATE: *February 27, 2004*

RELATED PCT APPLICATION NUMBER: PCT/US05/06437

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# APPLICATION DATA SHEET

Electronic Version v14

Stylesheet Version v14.0

<b>Title of Invention</b>	CONFORMING IONTOPHORETIC ELECTRODE
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<b>Application Type :</b>	provisional, utility
<b>Attorney Docket Number :</b>	IOM-P054

<b>Correspondence address:</b>	
<b>Customer Number:</b>	22876
	

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## TRANSMITTAL

Electronic Version v1.1

Stylesheet Version v1.1.0

<b>Title of Invention</b>	CONFORMING IONTOPHORETIC ELECTRODE	
Application Number :		
Date :		
First Named Applicant:	Ralph Koschinsky	
Confirmation Number:		
Attorney Docket Number:	IOM-P054	
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Submitted By:	Elec. Sign.	Sign. Capacity
Jody L Factor Registered Number: 34157	//jodyl.factor//	Attorney

Documents being submitted:	Files
us-request	IOMP054PV-usrequ.xml us-request.dtd us-request.xsl
us-fee-sheet	IOMP054PV-usfees.xml us-fee-sheet.xsl us-fee-sheet.dtd
application-body	aplIn-trans.xml us-application-body.xsl application-body.dtd wipo.ent mathml2.dtd mathml2-qname-1.mod isoamsa.ent isoamsb.ent isoamsc.ent isoamsn.ent isoamso.ent isoamsr.ent isogrk3.ent isomfrk.ent isomopf.ent isomscr.ent isotech.ent isobox.ent isocyr1.ent isocyr2.ent isodia.ent isolat1.ent isolat2.ent isonum.ent isopub.ent mmlextra.ent mmlalias.ent soextblk.dtd fig1.tif fig2.tif fig3.tif fig4.tif fig5.tif fig6.tif fig8.tif

Comments

## Description

# CONFORMING IONTOPHORETIC ELECTRODE

### BACKGROUND OF INVENTION

[0001] 1. Field of the Invention

[0002] The present invention relates in general to an iontophoretic delivery device. More particularly, this invention relates to an improvement in the use of a conforming iontophoretic electrode having a retention structure or material wherein the retention structure or material allows the electrode to be bent/molded into a specific shape to better conform to a body part.

[0003] 2. Background Art

[0004] It is widely known by those skilled in the art that the process of iontophoresis can be used in applying medication locally through a patient's skin as well as for use in delivering medicaments to and through the specific location of the skin such as the nose but not limited thereto. The

iontophoretic technique is generally known to those having ordinary skill in the art wherein the technique involves externally applying an electric field to the active delivery of medicaments; in essence, this technique drives ionized compounds through the skin. Thus, the iontophoretic delivery is non-invasive to and through a patient, and this delivery ensures that pain and infections, associated with injecting the medicament to a patient's skin, are ameliorated in the process.

## DETAILED DESCRIPTION

[0005] The present invention disclosed herein in general is a novel structural assembly wherein the assembly combines the use of an iontophoretic electrode with a retention structure or material to allow the electrode to be bent/molded into a specific shape to better conform to a body part. The structural assembly of this invention has, in a preferred embodiment, the structures as shown in Fig 1. In this figure, snap stud 1 is positioned in the center of skin fixation material layer 2, wherein shape retention device 3, component/skin fixation material and barrier 4, conductive element 5, snap eyelet 6, drug containment matrix 7, scrim type material 8, and release liner 9 are positioned sequentially. More particularly, in one embodiment,

ment of the present invention, the adhesive structural assembly is contemplated to conform to the nose but is not limited thereto. As shown in Fig 1, snap stud 1 and snap eyelet 6 are positioned in the center of the adhesive structural assembly to regulate the operation of iontophoretic delivery of medicament by controlling the time course and magnitude of current that flows through the electrodes of the iontophoretic electrode. While a specific example of regulating the operation of iontophoretic delivery of medicament has been disclosed, for illustrative purposes, it will be understood that other types of conventional configurations for regulating the operation of iontophoretic delivery of medicament known to those with ordinary skill in the art having the present disclosure before them are likewise contemplated for use.

[0006] Skin fixation material 2 may be a water impermeable skin adhesive sheet wherein the sheet may be composed of plastic tape, etc. The skin fixation material 2 may have an area covered with whole surface of the conductive element 5 and further cover the surrounding portion of the conductive element 5. The structural assembly does not have to have a specific geometric shape as it will be understood that other geometrical shapes as desired are likewise con-

templated for use.

[0007] Shape retention device 3 may be fabricated from any flexible/bendable material capable of conforming to or about an appendage, for example, tin, aluminum, or wire, etc. Shape retention device 3 can also be a film form or sheet form. Therefore, shape retention device 3 facilitates the iontophoretic assembly to bend/mold, and then to retain its shape after such bending/molding. It is also contemplated that conductive element 5 may be integrated with shape retention device 3. It should also be understood that the specific geometry of the shape retention element not be limited, nor should its specific positioning. What is important is that the iontophoretic electrode to be used (conventional or otherwise) include either a separate member, or an existing element combined with a retention element, which will enable the associated electrode structure to be retainably bent or molded into a desired orientation.

[0008] Accordingly, the retention device could include, among other things, an entire separate structure made of such bendable material (such as shown in Fig. 1); only a portion of the material being comprised of the bendable component; or, integrating a bendable component with other

conventional components of an iontophoretic electrode (such as the skin fixation layer 2 or conductive element 5). Furthermore, it is also contemplated that the iontophoretic electrode can include multiple sections or components comprising or including such bendable/moldable material, as would be appreciated by those having ordinary skill in the art. In addition to the use of a retention device, it is also contemplated that an adhesive material can be associated with, for example, the skin fixation material 2 to further aid in releasable securement of the conforming iontophoretic electrode to or about an appendage.

[0009] Conductive element 5 is preferably an active metal anode or cathode and can be an electric current dispersing material usually composed of a conductive rubber, a resin film, a carbon film, or a metal foil such as aluminum foil, etc. Conductive element 5 may include a conventional current collector, such as a screen, mesh or wire current collector fabricated from the same metal as that of the active anode or it may be fabricated from other metals such as, for example, brass which is coated with the same metal as the active anode or cathode metal. While specific examples of electrode materials and current collectors

have been disclosed, for illustrative purposes, it will be understood that other electrode materials known to those with ordinary skill in the art having the present disclosure before them are likewise contemplated for use.

[0010] Drug containment matrix 7 is prepared to an extent capable of keeping the self form-retaining property and is spread in a film form or sheet form. Drug containment matrix 7 is preferably fabricated from a material capable of temporarily retaining the medicament in solution. The solution may also contain supplemental agents, such as electrolyte, stability additives, preserving additives, pH regulating buffers, etc. Drug containment matrix 7 may comprise, for example, a natural or synthetic amorphous member, a natural or synthetic sponge pad, a natural or synthetic lint free pad, a natural or synthetic low particulate member – just to name a few. Indeed, numerous other materials that would be known to those with ordinary skill in the art having the present disclosure before them are likewise contemplated for use, including monolithic or layered viscoelastic solid hydro gels or liquid reservoirs contained with microporous membranes.

[0011] Scrim type material 8 is preferably fabricated from a material capable of holding drug containment matrix 7.

Scrim type material 8 may comprise, for example, a natural or synthetic amorphous member, a natural or synthetic lint free pad, a natural or synthetic low particulate member – just to name a few. It will be understood that the use of scrim type material 8 is not necessarily required and, accordingly, when not used, drug containment matrix 7 can be exposed directly to the skin of a patient, if desired. Indeed, numerous other materials that would be known to those with ordinary skill in the art having the present disclosure before them are likewise contemplated for use.

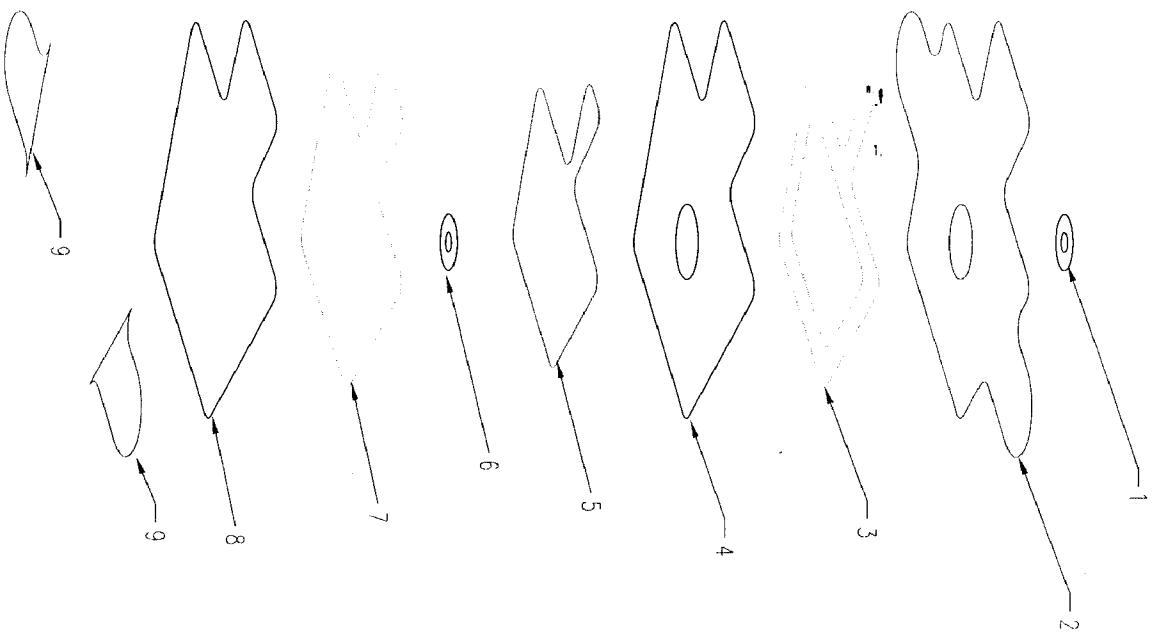
## Claims

- [c1]
  - 1. A conforming iontophoretic electrode comprising;
    - a. a skin fixation component, a conductive element, and a drug containment reservoir/matrix; and
    - b. A shape retention member for retaining the electrode in a particular shape.
- [c2]
  - 2. The conforming electrode according to claim 1, further including;
    - a. Adhesion means associated with the skin fixation component for operative releasable added securement to an appendage to which the conforming iontophoretic electrode is to be attached.

# CONFORMING IONTOPHORETIC ELECTRODE

## Abstract

The present invention is directed to a conforming iontophoretic electrode comprising a skin fixation component, a conductive element, and a drug containment reservoir/matrix and a shape retention member for retaining the electrode in a particular shape.



**COMPONENTS**

1. SNAP STUD
2. SKIN FIXATION MATERIAL
3. SHAPE RETENTION DEVICE
4. COMPONENT/SKIN FIXATION MATERIAL AND BARRIER
5. CONDUCTIVE ELEMENT
6. SNAP EYELET
7. DRUG CONTAINMENT MATRIX
8. SCRIMTYPE MATERIAL
9. RELEASE LINER

REV	ECO	DESCRIPTION	REVISIONS	DATE APPROVED
0A	XXX	INITIAL RELEASE	YY/YY/YY	ZZZ

**TOLERANCE**  
FRAC.  $\pm$  1/64  
X.XX  $\pm$  .01  
X.XX  $\pm$  .003  
ANGLE  $\pm$  1°  
DO NOT SCALE  
BREAK ALL EDGES

**SIGNATURES**  
DRAWN  
CHECKED  
ENGN.

**DATE**  
10/10/01  
IOMED

**DRAWING**  
TITLE  
SALT LAKE CITY, UTAH

**DRAWING**  
TITLE  
RHINO-ELECTRODE EXPLODED VIEW

**SIZE**  
B

**OLD PART #**  
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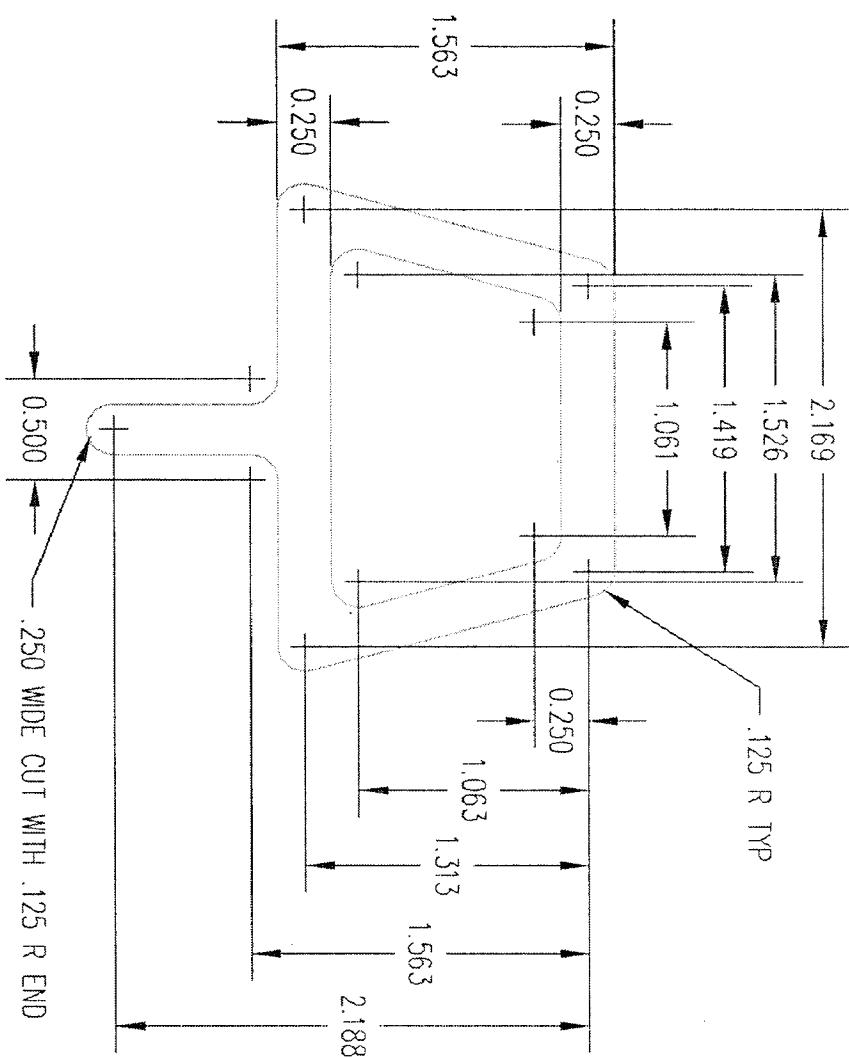
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**SHEET** 1 of 1  
**REV** 01

**FIGURE 1**

REV	ECO	DESCRIPTION	DATE	APPROVED	REVISIONS
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NOTE:  
 LEAVE 1 INCH BORDER OF BOARD ALL  
 AROUND CUTTING AREA

**TOLERANCE**

SIGNATURES

DATE

**IOMED**

.XX ± .010

DRAWN

SALT LAKE CITY, UTAH  
 DRAWING TITLE  
 RHINO RETAINER DIE

.XXX ± .015

CHECKED

FRACT. ± 1/64

DO NOT SCALE  
 THIS DRAWING

BREAK ALL EDGES

SCALE

N/A

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OLD PART #

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SHEET

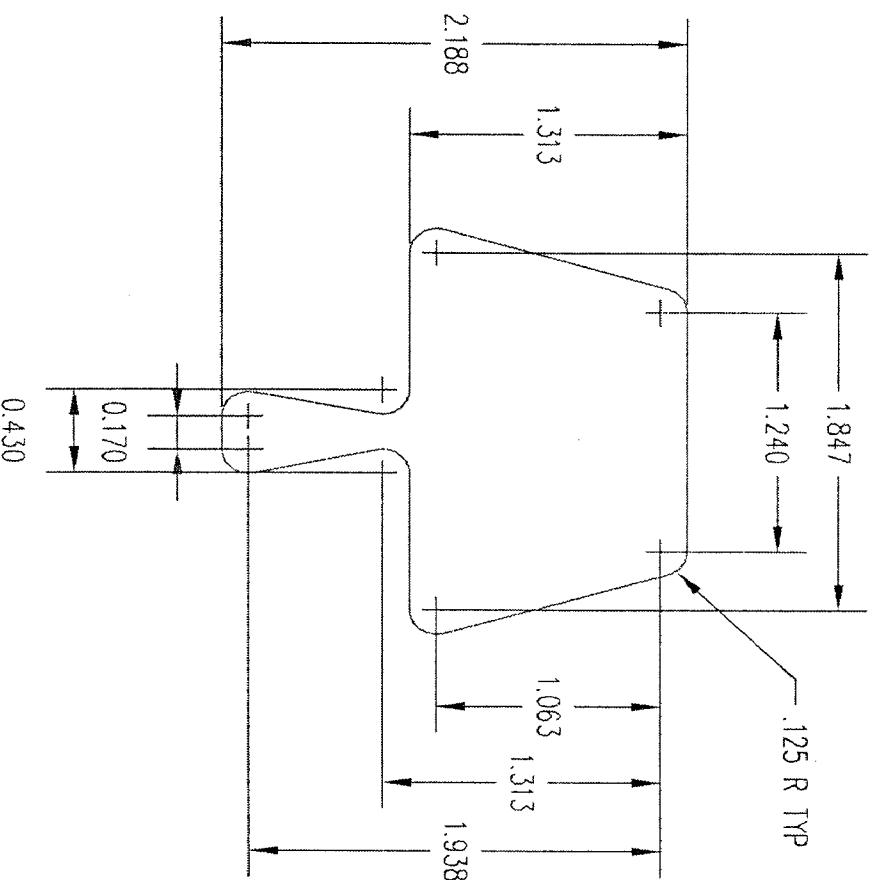
1 OF 1

REV.

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REV	ECO	DESCRIPTION	DATE	APPROVED
REVISIONS				

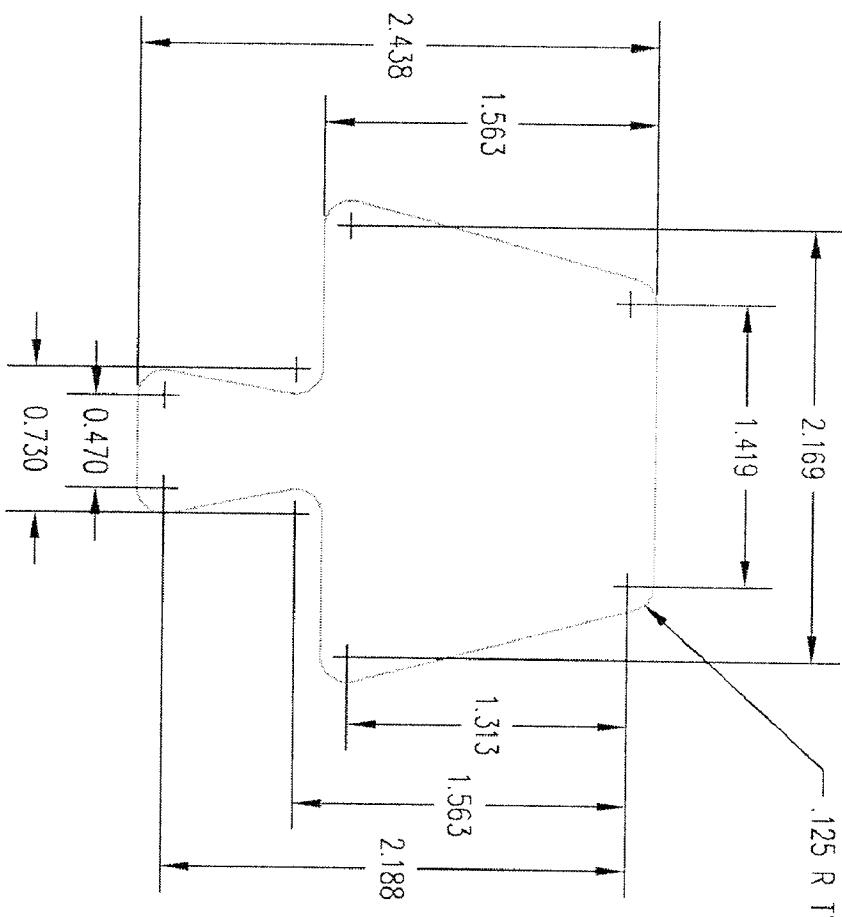


NOTE:  
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AROUND CUTTING AREA

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.XXX ± .015	CHECKED	DRAWING TITLE	RHINO CND DIE
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DO NOT SCALE THIS DRAWING			
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SCALE N/A	Sheet 1 of 1	REV. 01	

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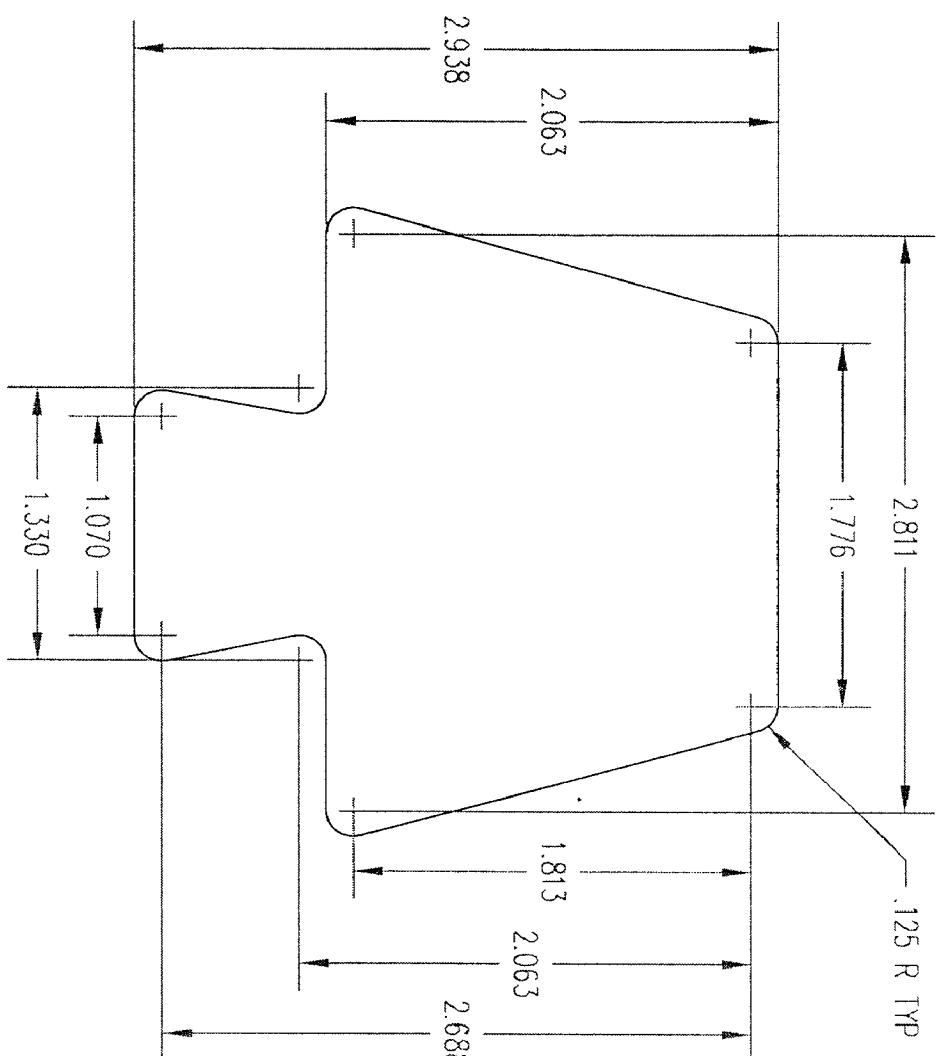
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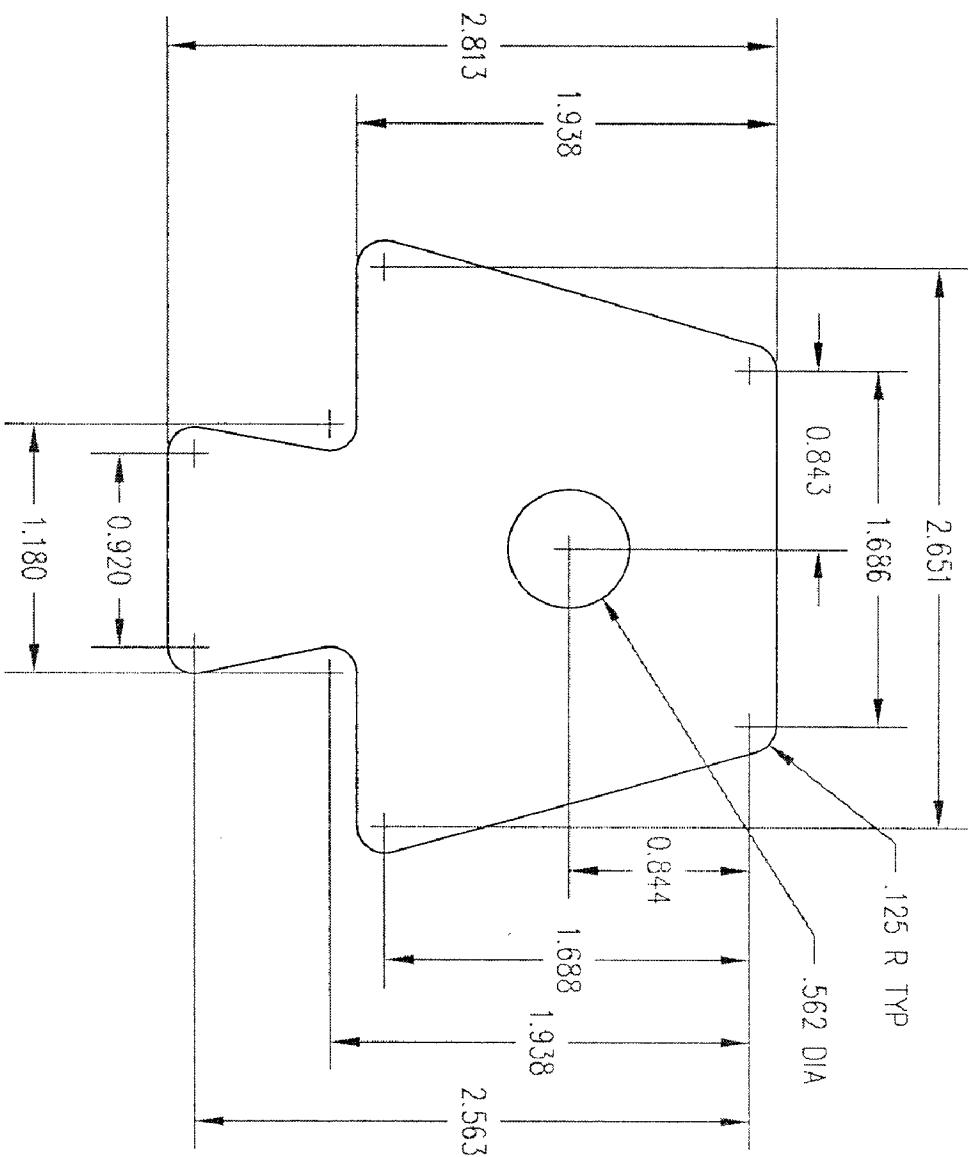
	SIZE	OLD PART #	DRAWING NUMBER	
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SALT LAKE CITY, UTAH

DRAWING TITLE  
RHINO SSCRM DIE

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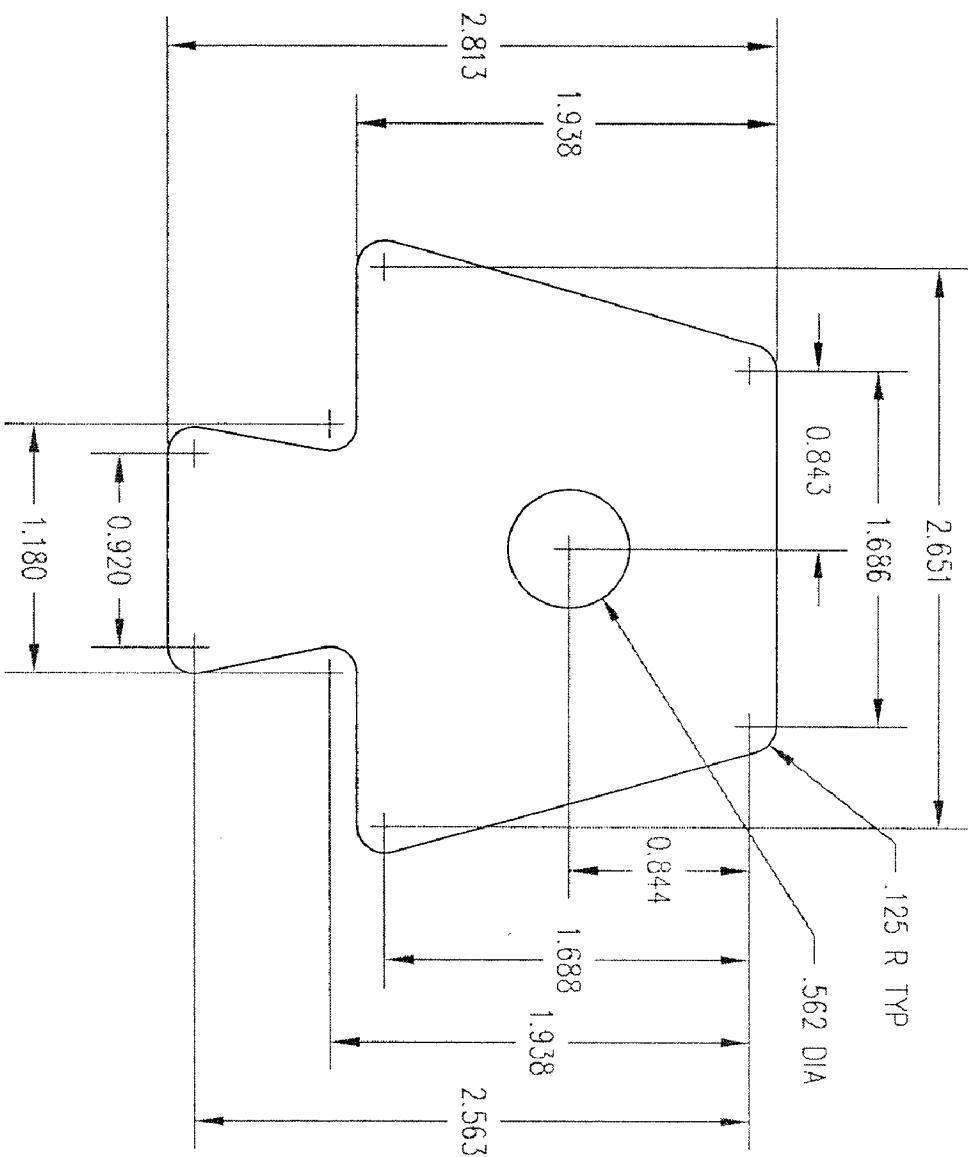


NOTE:  
LEAVE 1 INCH BORDER OF BOARD ALL  
AROUND CUTTING AREA

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					XXXXX
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BREAK ALL EDGES		SHEET 1 OF 1			

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<b>REVISIONS</b>				

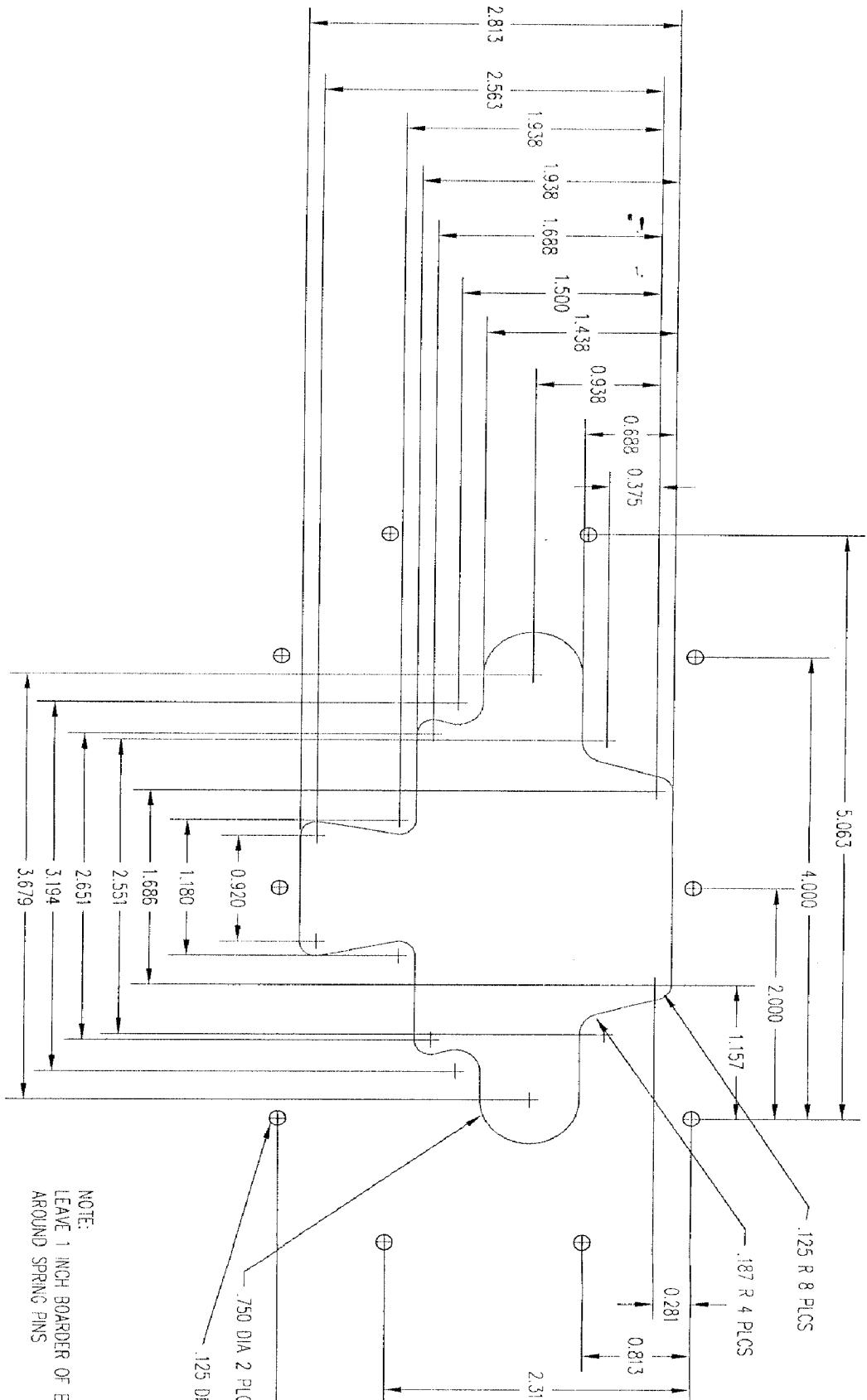


NOTE:  
LEAVE 1 INCH BORDER OF BOARD ALL  
AROUND CUTTING AREA

TOLERANCE		SIGNATURES		DATE	
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DO NOT SCALE THIS DRAWING		SIZE A	OLD PART #	DRAWING NUMBER	SALT LAKE CITY, UTAH
SCALE	N/A				RHINO BASE ADHESIVE DIE
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					REV. 01
BREAK ALL EDGES		SHEET 1 OF 1			

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REV : ECO      DESCRIPTION :      DATE : APPROVED  
0A      XXX      INITIAL RELEASE      MM/MM/YY      222  
REVISIONS



NOTE:  
LEAVE 1 INCH BORDER OF BOARD ALL  
AROUND SPRING PINS

TOLERANCE : SIGNATURES : DATE : IOMED

FRAC. ± 1/64	DRAWN	RKK	XX/XX/XX	SALT LAKE CITY, UTAH
XXX ± .01	CHECKED	YYYY	XX/XX/XX	DRAWING TITLE
XXX ± .015	ENGN.	RKK	XX/XX/XX	RHINO FINAL SHAPE D/E
ANGLE ± 1°				
DO NOT SCALE				
BREAK ALL EDGES				

SCALE : N/A      SHEET 1 OF 1      REV 01

XXX-XXXX-XXXX